federal register

WEDNESDAY, JUNE 1, 1977

PART III

CONSUMER PRODUCT SAFETY COMMISSION

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TRIS AND FABRIC, YARN, OR FIBER CONTAINING TRIS

Additional Interpretations as Banned Hazardous Substances

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT SAFETY COMMISSION

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINSTRATION AND ENFORCEMENT REGULATIONS

TRIS and Fabric, Yarn, or Fiber Containing TRIS; Additional Interpretations as Banned Hazardous Substances

AGENCY: Consumer Product Safety Commission.

ACTION: Additional banning interpretations of a statutory provision.

SUMMARY: On April 8, 1977, the Commission banned certain children's wearing apparel containing the chemical flame retardant TRIS and certain uncut fabric containing TRIS which is intended for sale to consumers for use in children's wearing apparel. On May 5, 1977, pursuant to an order of a Federal district court judge, the Commission also banned certain fabric, yarn, and fiber containing TRIS and TRIS itself which is used in or intended for use in children's wearing apparel. In this document the Commission is reissuing, under its own statutory authority rather than pursuant to the court order, its expanded ban of May 5, 1977.

DATES: The new banning interpretations are effective on June 1, 1977.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: On April 7, 1977, the Commission granted a petition from the Environmental Defense Fund concerning wearing apparel containing the chemical flame retardant Tris (2,3-dibrompropyl) phosphate ("TRIS"). The Commission published in the FEDERAL REGISTER on April 8 (42 FR 18850–54) an interpretation that certain TRIS-treated children's wearing apparel and certain TRIS-treated uncut fabric intended for sale to consumers for use in such apparel were banned hazardous substances under section 2(q)(1)(A) of the Federal Hazardous Substances Act (FHSA).

The apparel and fabric that was in interstate commerce on April 8 or introduced after that date was banned. In addition, such TRIS-treated apparel and fabric sold to consumers before April 8 but not yet washed was also banned.

On April 20, 1977, the American Apparel Manufacturing Association (AAMA) filed an action against the Commission in U.S. District Court for the District of Columbia. (The Commission had met with representatives of AAMA on March 31, 1977, to discuss economic and other factors relating to potential Commission action on TRIS). AAMA was seeking an order that would ban TRIS-treated fabric, fiber, and yarn that is already incorporated or intended to be incorporated into children's wearing apparel. A ban defined in this manner would require manufacturers of such TRIS-treated fabric, fiber, and yarn to repurchase the items from their customers under section 15 to the FHSA.

On April 22, 1977, representatives of the Independent Cutters and Sewers of Children's Sleepwear met with the Commission and submitted a petition to reconsider the form of the Commission's April 8 ban. The Commission believes that the ban issued below constitutes a granting of that petition. In addition, the EDF made a similar request in an April 26 letter to the Commission.

U.S. District Judge George L. Hart, on May 3, 1977, entered an order finding that the Commission acted arbitrarily and capriciously in limiting its April 8 band such that the full economic burden of the ban fell only on retailers and garment manufacturers. The court enjoined the Commission from enforcing the FHSA repurchase provisions against products banned on April 8 unless it expanded the scope of that ban within 10 days. Pursuant to Judge Hart's order, the Commission published in the FEDERAL REGISTER of May 5 (42 FR 22878–79) a ban which added to its ban of April 8.

The May 5 ban classified two additional categories of TRIS products as banned hazardous substances: (a) TRIS-treated fabric, yarn, and fiber which is used or intended for use in children's wearing apparel and (b) TRIS used or intended for use in children's wearing apparel. In both cases, those products sold before April 8 and already washed (or contained in wearing apparel that has already been washed) were not within the scope of the ban.

The additional categories of TRIS products did not ban any additional product sold to consumers. Rather, the expanded ban required additional manufacturers to repurchase the TRIS-treated wearing apparel and fabric that were banned on April 8.

On May 12 the U.S. Court of Appeals for the District of Columbia stayed Judge Hart's order and the Commission's May 5 ban. On May 19 the Court of Appeals lifted the stay and vacated Judge Hart's order upon the representation of the Commission that it would take prompt and decisive action in the matter. The Commission had indicated to the Court that it would expand the ban pursuant to its own authority rather than pursuant to Judge Hart's May 3 order, as the Commission did on May 5. The ban issued below constitutes the action that the Commission indicated it would take.

On May 23, in an action filed in the U.S. District Court for South Carolina by Springs Mills, a textile manufacturer, Judge Robert F. Chapman entered a preliminary injunction. The injunction restrains the Commission from applying or enforcing its TRIS regulations against Springs Mills, Inc., or aganist any TRIS-treated fabrics, yarns, or fibers manufactured by Springs Mills.

HAZARD

A. BACKGROUND

In March 1976 the Environmental Defense Fund (EDF), a health-oriented public interest organization, petitioned the Commission to require cautionary labeling for wearing apparel containing TRIS in surface concentrations in excess of 100 parts per million (ppm). This petition (HP 76–10) was based on data that showed that TRIS was capable of inducing mutations in Salmonella typhimurium when tested in both the presence and absence of metabolic activating systems (*1, 2, 3*).[1] The petition asserted at page 10 that this test has been shown to be a "highly reliable predictor" of carcinogenicity.

The Commission conducted a search of the existing literature in April 1976, and initiated a biological testing program in its own laboratories in June 1976 to evaluate the scientific issues raised in the petition. In addition, the Commission asked the National Cancer Institute (NCI) to expedite its rat and mouse carcinogenicity feeding studies involving TRIS that were already underway (*4*). The NCI agreed to provide the Commission with preliminary results from these studies as they became available (*5*).

On February 4, 1977 the Commission obtained the preliminary NCI test data (*6*). Within two weeks, the Commission's Bureau of Biomedical Science (BBS) provided a statistical analysis of the NCI rat and mouse bioassay study (*7*).

Based on its analysis of the same NCI preliminary test results, EDF petitioned the Commission on February 8, 1977 (HP 77–8), to ban the sale of wearing apparel containing TRIS (*8*). The Commission's technical staff met with Dr. Robert Harris, Dr. Joseph Highland, and Mr. Robert Rauch of EDF on February 18 to discuss this petition.

On March 2, the Commission met with Dr. Marvin Schneiderman, an Associate Director of the National Cancer Institute, and on March 8 the Commission met with the same EDF representatives that had met with the staff. All of these meetings were open to the public and transcripts are available (*9, 10, 11*).

Ms. Joanne Siegel and Dr. Reuben Epstein also petitioned the Commission, on February 1, 1977, to address the risk presented by wearing apparel containing TRIS (*12*). This petition (FP 77–1) requests the Commission to amend or revoke its flammability standard for children's sleepwear sizes 0–6X (16 CFR Part 1615), issued under the Flammable Fabrics Act, which has encouraged the use by manufacturers of TRIS as a flame retardant (although this standard imposes performance requirements concerning flame resistance, it neither prohibits nor requires the use of TRIS or any other chemical flame retardant).

On March 16, 1977, an updated draft of the TRIS bioassay results was released by NCI for the March 25 meetings of the

[1] The documents cited by parenthetical numbers correspond to the documents listed in the section on "References," below.

Data Evaluation and Risk Assessment Subgroups of the Clearinghouse on Environmental Carcinogens (*13*). These two subgroups act as statutory advisory groups to the NCI's Division of Cancer Cause and Prevention. At its March 25 meeting, the Data Evaluation Subgroup reviewed and approved the NCI bioassay results for TRIS (*14*).

Early in April 1977, the Commission completed its final report (*15*) on its subchronic dermal and oral ingestion studies along with radioactive ^{14}C–TRIS tracer studies and human lifetime risk estimates of cancer in the human population. These will be discussed in more detail in the section below.

B. CARCINOGENICITY

The Commission has carefully reviewed the preliminary data from the National Cancer Institute on the carcinogenicity of TRIS (*6*). Under the NCI testing program, begun early in 1974, rats and mice were fed TRIS daily at two dose levels. Weanling animals of both sexes were placed on diets containing 50 (low dose) or 100 (high dose) ppm TRIS in the case of rats; 500 (low dose) or 1000 (high dose) ppm TRIS in the case of mice; or no TRIS (control animals). After two years the surviving animals were sacrificed and examined for pathological changes.

The test mice that were fed TRIS developed tumors in the liver, the kidney, the lung, and the stomach and the test rats developed tumors in the kidneys (preliminary Table II in (*6*)). These test data establish TRIS as an animal carcinogen in two species and at multiple sites.

The Commission has no conclusive data that establish that TRIS has caused cancer in humans. Since cancers develop over many years and cannot be easily linked to particular causes, this is not unexpected. The Commission's Office of the Medical Director (OMD) believes that once a substance is established as an animal carcinogen it can never be assured as a safe substance for human exposure (*16*). In addition, OMD believes that all known human carcinogens have been shown to be carcinogenic in laboratory animals (*16, 17*).

Dr. Marvin Schneiderman of NCI has told the Commission that he knows of no chemicals that provide a high risk to animals but no risk to humans (pp. 43–44 of (*10*)). The February 1977 EDF petition asserts that TRIS is as potent or more potent in animals than a number of known human carcinogens (pp. 13–13a of (*8*)). Research Associate N. Kim Hooper and Professor Bruce N. Ames of the University of California, Berkeley's Department of Biochemistry, have stated in a March 21, 1977, letter to Chairman Byington (*18*) that TRIS is a more potent carcinogen than the human carcinogen benzidine or B–naphthylamine (p. 3 of (*18*)).

In a June 2, 1976, report, (*19*), the National Cancer Advisory Board states: "A major source of data on carcinogenicity comes from bioassays in experimental animals. Experience has indicated that, with one or two possible exceptions, compounds that are carcinogenic in humans are also carcinogenic in one or more experimental animal bioassay systems. In addition, several compounds first detected as carcinogens in experimental animals were later found to cause human cancer. Demonstration that a compound is carcinogenic in animals should, therefore, be considered evidence that it is likely to be carcinogenic in humans, unless there is strong evidence in humans to the contrary." (See also p. 11 of (*8*).)

C. MUTAGENICITY

The Commission has received several reports on the mutagenic potential of TRIS. Hooper and Ames (pp. 1 and 3 of (*18*)) focus on bacterial systems utilizing various grades of TRIS and TRIS-treated cloth. They also point out that TRIS is a potent mutagen in Drosophila, causing large numbers of recessive lethal mutations in offspring. Moreover, they assert that TRIS is capable of causing damage to DNA synthesis in human cells in tissue culture.

The general assertion of Hooper and Ames is that TRIS is mutagenic and "likely to cause genetic birth defects in the offspring of children exposed to it" (p. 1 of (*18*)). They base this conclusion on their belief that TRIS can be absorbed through the scrotum and could effect spermatogenesis.

Dr. M. Prival, in an article entitled, "Tris (2, 3-Dibromopropyl) Phosphate: Mutagenicity of a Widely Used Flame Retardant" (*20*), has found TRIS to be mutagenic in histidine-requiring strains of Salmonella typhimurium (although he does not believe his results conclusively demonstrate that TRIS is a carcinogen).

It must be noted that the BBS analysis of bone marrow chromosomes obtained from rats which received either a single or multiple daily oral dose of TRIS five days per week for 13 weeks did not demonstrate any chromosome aberrations (*15*).

D. EXPOSURE

TRIS is incorporated into some wearing apparel in at least two ways, according to information obtained by the Commission's Bureau of Engineering Sciences (*21*). Certain wearing apparel is manufactured from fabric knitted or woven from fibers that contain TRIS. Other apparel is manufactured from fabric that has been topically treated with TRIS. In both cases, some TRIS that is not tightly bound or contained within the fibers can be removed from the garment by the sucking, or "mouthing," of an infant on the sleeve or other portion of the garment. The TRIS that infants can ingest in this manner is a source of exposure of infants to TRIS. Another source of exposure is absorption through the skin.

The Commission has reviewed various estimates of the amount of TRIS to which a child may be exposed. These estimates come from a March 16, 1977, report prepared by the Bureau of Biomedical Science (*22*); from a March 8, 1977, report by Robert H. Harris, Ph. D., of EDF, entitled Estimating the Cancer Hazard to Children from Tris-treated Sleepwear (*23*); and from the March 21 Hooper and Ames letter (*18*). The general assumptions underlying all of these estimates are (a) that a child mouths the garment and ingests available TRIS; (b) that there is absorption through the skin; and (c) that the child wears numerous garments over a period of time containing various amounts of available TRIS.

(1) *Bureau of Biomedical Science.* BBS has prepared a range of estimates on the amount of TRIS to which a child could be exposed over a 6-year period, both from skin absorption and from mouthing. Their estimates of total TRIS absorbed range from 2.5 to 77.4 mg/kg, depending upon the body area exposed to TRIS-treated garments.

In the Commission's subchronic toxicity and dermal penetration studies, the groups of rats which received daily doses of TRIS by the oral route (25 mg/kg and 250 mg/kg) demonstrated renal nephrosis following a 13 week period. The weekly dermal application of 1 ml/kg of undiluted TRIS to clipped rabbits produced renal nephrosis and testicular atrophy also at the end of a 13 week period. These data correlate well with NCI's finding of renal carcinoma in rats and mice at a 2-year period.

The degree of penetration of TRIS in rabbit and rat of both sexes was determined following dermal application of ^{14}C-TRIS at 0.9 ml/kg and at 0.05 ml/kg. Radiolabeled TRIS from TRIS-treated cloth was also shown to penetrate the skins of rabbits. Penetration was enhanced by the presence of urine on the cloth. The kidney was found to be the organ of highest specific radioactivity in all cases. Most of the absorbed radiolabeled TRIS was excreted in the urine (for more detail see (*15*)).

(2) *Environmental Defense Fund.* EDF estimates of the total lifetime exposure for a child range between 0.085 mg/kg to 85 mg/kg (p. 15 of (*23*)) and are based primarily upon dermal absorption for a 10 or 20 kg child exposed to one, ten, or 20 pairs of TRIS treated sleepwear.

(3) *Hooper and Ames.* Based on one year of exposure of a 7 kg. child, Ames and Hooper estimate that the exposure due to dermal absorption would be 70 mg/kg/year and the dose a child receives by sucking is estimated as one percent of that obtained through skin absorption (*18*).

E. RISK ASSESSMENT

The Commission has considered risk assessments that are based on the estimates of exposure cited in Section D, above. The methods used to prepare the estimates are described in a March 1977 paper entitled, Estimates of Human Lifetime Carcinogenic Risk from Exposure to TRIS, prepared by Drs. Charles Brown, Marvin Schneiderman, and Kenneth Chu of the National Cancer Institute (*24*). The statistical extrapolations are based on the use of two mathematical models: the single-hit model (linear no threshold) and the log-probit model (Mantel-Bryan). The use of these

mathematical models and the extrapolations from animals to man rest on the following assumptions: (a) the animal dose can be converted to an "equivalent" human exposure level; (b) mouse and man, and rat and man, have equal sensitivities to TRIS; (c) infants and children are no more, or less, sensitive to TRIS than are adults; and (d) the dose given to an animal during its entire life can be converted to an equivalent daily dose during a specific period of time which is less than a lifetime.

(1) *Bureau of Biomedical Science.* BBS has projected cancer incidence rates based on its exposure estimates and on data from the NCI study. These projected rates show the kidney to be the primary target organ. The best estimate of BBS (*25*) is approximately 300 kidney cancers per million male population. For females the projected rate is about one-fifth that of males.

Based on the single hit model the BBS estimates for lifetime risk of cancer of the kidney is between 60 and 1,800 cases per million male population. For the log probit model the estimates range from 25 to 5,100 cases per million males. All of these estimates are lifetime risk or lifetime incidence estimates.

(2) *Environmental Defense Fund.* EDF also provided its estimates on human exposure to NCI which used the same models, and these data provided estimates of a lifetime incidence of cancer of as high as 6,000 per million male population, based on maximum exposure, the rat kidney and the log probit model.

(3) *Hooper and Ames.* Hooper and Ames estimate that for one year of exposure, 1.7 percent of the children would develop cancer (17,000 cases/million). An exposure throughout childhood would give a higher risk (p. 8 of (*18*)).

F. EFFECT OF WASHING

There is evidence both from the March 1976 EDF petition (*1*) and from reports of the Commission's Bureau of Engineering Sciences (*21*) that the amount of TRIS that can be easily removed from a garment is appreciably reduced by repeated washings. The March 1976 petition states at page 5 that "* * * most of the surface TRIS could be washed out of the fabrics, which implies that laundering in use will reduce exposure to TRIS. For example, two samples of different polyester fabric had 70,000 ppm and 37,500 ppm of surface TRIS before, and 35 ppm and 100 ppm of surface TRIS after washing, respectively. It would appear from these studies that during the first three washings of polyester fabrics, surface TRIS can be reduced by greater than 95 percent, while the total amount in the fabric will be reduced by only about 12 percent." (The fabric containing 70,000 ppm had been specifically treated for test purposes and has not been commercially marketed.)

According to the BBS review of literature data, acetate fabrics contain 65–600 ppm "surface TRIS"[2] (more uniform and lower concentrations that polyester) and polyester fabrics contain 260–37,500 ppm surface TRIS. Although BES stresses the limited reliability of these figures, estimates from the studies show that washing removes up to 85 percent of surface concentration in acetate fabrics and from 21 to 82 percent in polyester fabrics.

G. EFFECT ON FLAMMABILITY INJURIES

Much of the use of TRIS in wearing apparel is to meet the Commission's flammability standards for children's sleepwear (16 CFR Parts 1615 and 1616). The Commission's Bureau of Epidemiology (BEP) believes, based on an analysis of injury information and on an article on children treated by physicians that children who are burned while wearing flame-resistant sleepwear tend to sustain less extensive burns than children who are burned while wearing non-flame-resistant sleepwear (*26*). Date indicate that the number of deaths to children ages 1–4 due to clothing ignition decreased following the effective date of the standard for children's sleepwear in sizes 0–6X.

Because the Commission's flammability standards for children's sleepwear are performance standards, the Commission assumes that manufacturers can and will comply with the standard without using TRIS or any other chemical which presents a hazard to the consumer. There are fabrics which meet the standard without using any chemical flame retardants (*27*).

MARKETING FACTORS

Garments treated with TRIS are made of either 100 percent polyester or acetate and triacetate blends. There is no certain way to distinguish among 100 percent polyester fabrics that are untreated, treated with TRIS, or treated with another flame retardant. The Commission understands, however, that all acetate and triacetate fibers used in children's sleepwear fabrics contain TRIS.

The Commission has found that flame resistant garments currently on the market are: (a) children's sleepwear, sizes 0–14, for which the flame resistant requirement is mandatory, and (b) those which resulted from voluntary programs undertaken by a few major retailers. The Commission believes that there is no significant inventory of flame-resistant garments resulting from voluntary programs at this time (p. 4 of (*27*)).

The Commission's Bureau of Economic Analysis (BEA), in a March 21, 1977 report (*28*) has estimated that 18 million garments, over one-third of the spring 1977 production of children's sleepwear, contain TRIS. With inventories taken into account, the portion of TRIS-treated merchandise was estimated in April 1977 to be over 40 percent of all children's sleepwear in the retail pipeline, or about 20 million garments. About 10–20 percent of this had already been sold to consumers. In addition, BEA estimated that about 7 million square yards of TRIS-treated fabric was then in inventory with fabric and garment producers.

BEA believes that a small number of national retail chain outlets and very large discount stores account for more than 55 percent of children's sleepwear sales, while department stores account for 20 percent, and specialty and variety stores account for less than ten percent of annual sales.

ENVIRONMENTAL IMPACT

The Commission has considered the environmental impact of its ban. A preliminary environmental assessment was available when the April 8 ban was published (*29*). A final assessment is now available (*30*), and it primarily addresses the questions of a) disposal of TRIS-treated garments, fabrics, fibers, and yarns and b) the use of substitute chemical flame-retardants and substitute end-use products. The Commission has begun work on an environmental impact statement.

Because of the emergency circumstances of the ban of TRIS products, the Commission has been in contact with the Council on Environmental Quality (CEQ) concerning alternative arrangements for complying with the CEQ guidelines on the National Environmental Policy Act. A Commission letter to CEQ on this subject and a response indicating CEQ's concurrence are available (*31, 32*).

REFERENCES

The parenthetical numbers used in the above portion of the preamble refer to the following documents, studies, and other materials:

(*1*) March 24, 1976, petition (HP 76–10) from the Environmental Defense Fund.

(*2*) Letter from Glenn E. Schweitzer, Director, Office of Toxic Substances, EPA to Stanley R. Parent, Executive Director, CPSC, October 29, 1975, and a similar letter to Dr. David Rall, Director, NIEHS, on the same date.

(*3*) Ames, B., in a letter to Dr. B. L. Van Duuren, New York University Medical Center, January 28, 1976.

(*4*) November 8, 1976, letter from Chairman S. John Byington to Frank J. Rauscher, Ph. D., Director of the National Cancer Program of NIH.

(*5*) December 3, 1976, letter from Robert A. Squire, D.V.M., Ph. D., Acting Chief of the Carcinogen Bioassay and Program Resources Branch at NIH, to Chairman Byington.

(*6*) Preliminary NCI data on TRIS bioassay feeding studies.

[2] The term "surface TRIS" is merely one of convenience. Whether or not the easily removable TRIS is literally on the surface of the fibers is unknown. The more fundamental distinction would appear to be between that amount of TRIS that is loosely bound to fibers and that which is more tightly bound, wherever it may be.

(7) Memo from R. M. Hehir to Don Clay on February 16, 1977, entitled "BBS Statistical Analysis of NCI Cancer Bioassay Report on TRIS (2,3-dibromopropyl) phosphate, with attachments.

(8) February 8, 1977, petition (HP 77-8) from the Environmental Defense Fund.

(9) Transcript of February 18, 1977, meeting between Commission staff and EDF representatives.

(10) Transcript of March 2, 1977, Commission meeting with Dr. Schneiderman, NCI.

(11) Transcript of March 8, 1977, Commission meeting with EDF representatives.

(12) February 1, 1977, petition (FP 77-1) from Ms. Joanne Seigel and Dr. Reuben Epstein.

(13) March 16, 1977, NCI draft Bioassay of TRIS (2,3-dibromopropyl) phosphate for possible carcinogenicity.

(14) March 26, 1977, memorandum from R. M. Hehir to Michael Brown and attached meeting log.

(15) Final report—Subchronic and Radioactive ^{14}C Tracer Studies of TRIS (2,3-dibromopropyl) phosphate in Laboratory Rodents, prepared by Bureau of Biomedical Science/CPSC, April 1, 1977.

(16) February 15, 1977, memorandum from Albert P. Esch, Medical Director, on extrapolation of risk from animals to humans.

(17) February 18, 1977, memorandum from Rita A. Orzel, Ph. D., of the Commission's Division of Human Toxicology and Pharmacology in OMD, same subject as 16 above.

(18) March 21, 1977, letter from Hooper and Ames on hazards of carcinogenicity and mutagenicity to humans through dermal absorption and ingestion of TRIS.

(19) June 2, 1976, National Cancer Advisory Board report.

(20) "TRIS (2,3-dibromopropyl) phosphate: Mutagenicity of a Widely Used Flame Retardant," Vol. 195, (pp. 76-78) Jan. 7, 1977, by Drs. Michael J. Prival, Elena C. McCoy, Bezalel Gutter, and Herbert S. Rosenkranz.

(21) March 15, 1977, memorandum from Margaret Neily, BES entitled "Review of Literature on Availability of TBPP from Treated Fabrics."

(22) March 16, 1977, memo from BBS entitled "Chemical Availability of TRIS (2,3-dibromopropyl) phosphate (TBPP) and Dermal and Oral Absorption Models for Three Possible Use Patterns".

(23) March 8, 1977, Harris report entitled "Estimating the Cancer Hazard To Children from Tris-treated Sleepwear."

(24) March 1977 Brown, Schneiderman, Chu paper entitled "Estimates of Human Lifetime Carcinogenic Risk from Exposure to Tris."

(25) March 17, 1977, Bayard to Hehir memo entitled "Preliminary Analysis of Tris Induced Human Lifetime Risk to Cancer."

(26) June 1976 BEP report on sleepwear entitled "Tris and Children's Sleepwear."

(27) February 25, 1977, memorandum of James Sharman, OEX, with attached marketing study.

(28) March 21, 1977, BEA report entitled "Availability of Garments Treated with TBPP."

(29) Preliminary environmental assessment of a TRIS ban.

(30) Final environmental assessment of a TRIS ban.

(31) April 5, 1977, letter to CEQ Acting General Counsel David Tunderman.

(32) April 22, 1977, CEQ response to Commission's letter.

Statutory Findings

Section 2(f)(1)(A) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f)(1)(A)) defines "hazardous substance" as "any substance or mixture of substances which is toxic * * * if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." Section 2(g) of the FHSA (15 U.S.C. 1261(g)) states that "[t]he term 'toxic' shall apply to any substance * * * which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." Section 2(q)(1)(A) of the FHSA (15 U.S.C. 1261(q)(1)(A)) defines "banned hazardous substance" as "any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted."

Section 15 of the FHSA (15 U.S.C. 1274) concerns the repurchase of banned hazardous substances by manufacturers and others in the chain of distribution. The Commission's ban of TRIS products involves more than one type of manufacturer, including manufacturers of the affected chemical, fiber, fabric, yarn and garments. Because such a multiple manufacturer situation exists, the Commission must clarify a number of questions concerning repurchase that have been raised. The Commission expects to issue such a clarification, probably by publication in the Federal Register, as soon as possible.

The Commission has already found that TRIS-treated children's wearing apparel and TRIS-treated uncut fabric intended for sale to consumers for use in such apparel are banned hazardous substances if they were in interstate commerce on April 8, 1977, were or are introduced into interstate commerce after that date, or were sold to consumers before that date but are not yet washed (42 FR 18853). The Commission found that such items are "toxic" within the meaning of section 2(g) of the FHSA and that they may cause substantial illness as a result of their exposure to children within the meaning of section 2(f)(1)(A) of the FHSA.

The Commission's expanded ban, issued below, does not ban any products sold at retail that were not already banned on April 8. Rather, it bans certain components of the products banned on April 8. Therefore, the statutory findings as to the risk presented are identical.

The Commission decided that the only products sold to consumers before April 8 that were banned were those products not yet washed by consumers. There were a number of reasons why the Commission framed its ban in this manner.

Evidence before the Commission indicated that washing removes much of the TRIS in clothing and fabric that might otherwise be available for absorption and ingestion. The Commission believes that most of the clothing and fabric that consumers bought before April 8 has been washed one or more times. The Commission did not find that TRIS-treated clothing and fabric bought before April 8, and already washed by consumers, is necessarily "safe."

It should also be noted that the Commission believes that TRIS-treated clothing, fabric, yarn, and fiber not yet sold by April 8, even if washed during one or more stages of the manufacturing processes, will cause substantial illness. The Commission's test data and other evaluations of the risk of TRIS products were based for the most part on garments already manufactured and ready for retail sale.

There were other important reasons, besides washing by consumers, why the Commission framed its ban in the manner it did. These include the massive marketplace disruption that such a ban would undoubtedly involve; the increased and needless anguish that parents of children who have been exposed to the washed clothing and fabric would feel; and the practical difficulties associated with tracing and repurchasing approximately 120 million items that are years old and often lacking identifying labels.

As already mentioned, sections 2(f)(1)(A) and 2(g) of the FHSA define the terms "hazardous substance" and "toxic." The Commission believes that the TRIS products it has banned, on April 8 and in the order issued below, fall clearly within both of those definitons. Since they are also intended for use by children, they are banned by section 2(q)(1)(A) which defines the term "banned hazardous substance." As the legislative history states, "[t]oys or other articles intended for use by children which bear or contain a hazardous substance are banned by the language of the bill itself * * *" (Senate Report No. 1551, 89th Cong., 2d Sess., page 2).

The Commission has the discretion, under section 3(a) of the FHSA, to conduct a rulemaking proceeding before it declares a substance to be a hazardous substance. This provision is available for use "[w]henever in the judgment of the [Commission] such action will promote the objectives of this Act by avoiding or resolving uncertainty as to its application * * *".

If the Commission had any uncertainty about whether the TRIS products were hazardous substances, it would have conducted a rule-making proceeding according to the procedures prescribed in sections 701 (e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act, as required by section 3(a)(2) of the FHSA.

The Commission found, however, that the evidence supporting the risk of illness presented by the TRIS products is overwhelming. The two-year NCI feeding study shows the potency of TRIS as a carcinogen in animals. The strong link between animal carcinogens and human carcinogens is supported by numerous authorities. The available tests concerning absorption of TRIS through the skin are persuasive and the resulting risk assessments performed by NCI have enormous implications for the health of children who would continue to wear

TRIS-treated clothing. The fact that the cases of cancer will not appear immediately does not minimize the seriousness of the present risk.

Separate from the question of a proceeding under section 3(a) of the FHSA, there is the consideration that the Administrative Procedure Act imposes requirements on agencies for notice of proposed rulemaking, opportunity for public participation, and a delayed effective date (5 U.S.C. 553). However, these requirements are not applicable to interpretive rules or general statements of policy and are therefore not applicable to the interpretation announced in this document. Even if the rules were to be considered general rulemaking, the Commission for good cause finds that notice and public comment and a delayed effective date are contrary to the public interest because the statutory intent and structure of the FHSA is that children's articles that may cause substantial illness based on their toxicity must be banned without any delay.

Although codification in the Code of Federal Regulations is not required in this instance, the Commission believes that a precise articulation of what products are banned hazardous substances is necessary and appropriate. Consumers and the affected industries will be best informed of their repurchase rights and obligations by this method. As was done on April 8, the Commission is therefore listing the banned TRIS products along with other children's products previously banned.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (sections 2 (f)(1)(A), (g), (q)(1)(A) and 10(a), 74 Stat. 372, 374, as amended 80 Stat. 1305; 15 U.S.C. 1261 (f)(1)(A), (g), (q)(1)(A), 1269(a)) and under authority vested in the Consumer Product Safety Commission by the Consumer Product Safety Act (section 30(a), 86 Stat. 1231; 15 U.S.C. 2079(a)), the Commission amends 16 CFR 1500.18(d) by adding the following:

§ 1500.18 Banned toys and other banned articles intended for use by children.

* * * * *

(c) [Reserved]

(d) *Toys and other children's articles presenting toxicity hazards.* Under the authority of Section 2(f)(1)(A), 2(g), 2(q)(1)(A), and 10(a) of the act, the Commission has declared that the following articles are banned hazardous substances because they are toys or other articles intended for use by children that are hazardous substances, or bear or contain hazardous substances in such manner as to be susceptible of access by a child to whom they are entrusted, based on the fact that they may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children, because of their toxicity:

* * * * *

(3) All fabric, yarn, or fiber which contains TRIS (2,3-dibromopropyl) phosphate and which is used or intended for use in children's wearing apparel (whether the fabric, yarn, or fiber is cut, uncut, or already incorporated in children's wearing apparel) and which is interstate commerce on April 8, 1977, or which is introduced into interstate commerce after that date, or which has not yet been washed (even if it has been sold before that date);

(4) All TRIS (2, 3-dibromopropyl) phosphate which is used or intended for use in children's wearing apparel and which is in interstate commerce on April 8, 1977, or which is introduced into interstate commerce after that date, or which is in such apparel which is unwashed and is in the hands of consumers.

If any provision of the April 8, 1977, order or this addition, or the application of such provision to any person or circumstance, shall be held invalid, no other provision of the April 8, 1977, order, or this addition thereto, shall be affected thereby.

Dated: May 27, 1977.

RICHARD E. RAPPS,
Secretary, Consumer Product Safety Commission.

[FR Doc.77-15619 Filed 5-31-77;8:45 am]